

Institute of Pharmacy
Nirma University of Science & Technology
B. Pharm. Hons. (5 Year Integrated Programme)
Semester – IX

Course Name: Advanced Pharmacotherapeutics

THEORY (DETAILED SYLLABUS)	L	P	C
	3	6	6

Pharmacotherapeutics management of following diseases :

Cardiovascular disorders :

Hypertension, Heart Failure, Cardiac arrhythmias, Ischemic Heart diseases, Acute coronary syndrome and Thromboembolic disorders.

Respiratory disorders :

Chronic obstructive pulmonary diseases and Bronchial Asthma

Hematological diseases :

Anemia and various coagulation disorders

Rheumatic diseases :

Rheumatoid arthritis and osteoarthritis, osteoporosis, Gout and Hyperuricemia and Systemic Lupus Erythematosus.

Gastrointestinal system :

Peptic ulcer disease, Gastroesophageal Reflux disease, Chronic inflammatory Bowel disease, Hepatitis, Alcoholic Liver Diseases, Acute and chronic liver failure, Cirrhosis and Pancreatitis.

Renal disorders :

Acute Renal failure, Chronic Renal failure, End stage renal failure

Endocrine disorders :

Diabetes Mellitus, Thyroid & Parathyroid diseases, Adrenocortical dysfunction,

Psychiatric and Neurologic Disorders :

Epilepsy, Parkinsonism, Schizophrenia, Depression and Mania, Anxiety, Insomnia, Alzheimer's disease, Migraine, Drug addiction

Infectious Diseases:

Urinary Tract Infections, Enteric infections, Upper Respiratory tract infections, Pneumonia, Tuberculosis, Central nervous system infections, Bone and joint infections, Sexually Transmitted Diseases and AIDs and infections in immunocompromised patients.

Oncologic diseases :

Acute and chronic leukemia, Lymphomas, Gastrointestinal and liver cancers, Lung cancers, prostate and Gynecologic cancers, Melanomas and Breast cancer.

Ophthalmologic disorders :

Glaucoma, Cataract etc.

Skin diseases**Immunological disorders****Practicals**

The Practicals are aimed to impart in-depth thorough knowledge and skills necessary to enable the student to understand the Pathophysiology of common diseases and rationale for drug therapy by taking up various case-studies or by Hospital postings (preferable) in various departments. The students should learn the therapeutic approach to management of these diseases, controversies in drug therapy, importance of preparation of individualized therapeutic plans based on diagnosis, should be able to understand the need to identify the patient-specific parameters relevant in initiating drug therapy, monitoring therapy and their management. The students are required to maintain a record of various case presentations (covering most common diseases).

Books Recommended:

1. Clinical Pharmacy and Therapeutics – Roger and Walker, Churchill Livingstone Publications
2. Applied Therapeutics - The clinical use of Drugs. Lloyd Young and Koda-Kimble MA
3. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
4. Textbook of Therapeutics : Drug and Disease Management. 7th Edition. Editors - Eric T. Herfindal and Dick. R. Gourley, Williams and Wilkins.

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Semester – IX

Course Name: Clinical Pharmacy Practice

THEORY (DETAILED SYLLABUS)

L P C
3 6 6

1. Definitions, development and scope of Clinical Pharmacy Practice.
2. Introduction to daily activities of a clinical pharmacist
3. Patient data analysis
4. Clinical Laboratory tests used in the evaluation of disease states, and interpretation of test results
5. Drug and poison information
6. Clinical Pharmacokinetics
7. Clinical Application of Statistical Analysis

Practicals

Students are expected to perform Practical in the following areas covering the topics dealt in theory class :

- Answering drug information questions
- Patient medication counseling
- Case studies related to laboratory investigations
- Patient medication history interview
- Critical appraisal of recently published articles in the biomedical literature which deals with a drug or therapeutic issue.

Books Recommended :

1. Basic Skills in interpreting laboratory data – Scott LT, American Society of Health System Pharmacists Inc.
2. Biopharmaceutics and Applied Pharmacokinetics – Leon Shargel, Prentice Hall Publication
3. Clinical Pharmacokinetics _ Rowland and Tozer, Williams and Wilkins Publication.
4. Clinical Laboratory Tests : Values and Implications; 3rd ed., Spring House, Pennsylvania, 2001.

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Semester – IX

Course Name: Clinical Pharmacokinetics

THEORY (DETAILED SYLLABUS)

L P C

3 - 3

1. Introduction to clinical pharmacokinetics

Importance, clinical significance of drug absorption, distribution and elimination process and influence of disease on these processes, Pharmacokinetic models, parameters and its applications in clinical settings, brief study of absorption, disposition and metabolite kinetics

2. Dosage regimens

Objectives, development of constant-rate and multiple-dosage drug regimen, applicability of pharmacokinetics to dosage regimen and study design.

3. Therapeutic drug monitoring

Criteria for measuring drug serum concentrations and its data interpretation, free drug concentration monitoring, rationale for therapeutic drug monitoring in renal and liver impairment and approaches to drug dose alteration in these situations

4. Pharmacokinetic variation and model independent relationships

Sources of pharmacokinetic variation and its effect on pharmacokinetic parameters, genetically determined variations in pharmacodynamics, clinical importance of correct sample collection, storage and assay, calculations of model independent pharmacokinetic parameters such as MRT, total body clearance, volume of distribution at steady state

5. Clinical pharmacokinetics in the adults

Differences in drug handling in the adults compared to child, clinical implications of these differences for drugs and the ways to solve these problems.

6. Clinical pharmacokinetic study for different drug therapy like aminoglycosides, antiepileptics, digoxin, theophylline, lithium and vancomycin

Book Recommended

1. Rowland M., Tozer N., Thomas, Clinical Pharmacokinetics- Concepts and Application by Tozer, B. I. Waverly Pvt. Ltd., New Delhi.
2. Dhillon S., Kostrzewski, A., Clinical Pharmacokinetics, Pharmaceutical Press, London.
3. Dipiro, J., Spruill, W., Wade, W., Blouin, R., Pruemer, J., Concepts in clinical pharmacokinetics, American society of health-system pharmacists, Inc.
4. Burton, M., Shaw, L., Schentag, J., Evans, W., Applied pharmacokinetics & pharmacodynamics, Lippincott Williams & Wilkins, Philadelphia
5. Shargel L., Applied Biopharmaceutics and Pharmacokinetics and Mc-Graw Hill, New York.
6. Kimki C., Hui, Duffull B., Stephen, Simulation for the designing clinical trials by Marcel Dekker Inc., New York.
7. Notari, E., Robert, Biopharmaceutics and Clinical Pharmacy- An Introduction by Marcel Dekker Inc., New York.

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Semester – IX

Course Name: Pharmacoeconomics

THEORY (DETAILED SYLLABUS)

L P C

3 - 3

1.Introduction to cost and outcomes in health and medicine

Define cost and outcomes research and its potential applications in health and medicine

2.Cost-minimization, cost-benefit, and cost-effectiveness analysis

Compare and contrast the various methods for economic evaluation of health care programs
Define and interpret the incremental cost-effectiveness ratio (ICER)

3.Cost-utility analysis, league tables

Need for CUA, Quality-adjusted life-years (QALYs), Ranking interventions, Making decisions using CUA

4.Decision modeling

Define decision-analysis and interpret studies utilizing this methodology, Understand rules for decision modeling

5.Measuring costs

Differentiate between marginal and average costs, medical and nonmedical costs, and direct and indirect costs, Explain the differences between actual costs, provider charges, and payer reimbursement, Understand rating scales, standard gamble, time trade-off

6. Critical evaluation of the literature and of cost-effectiveness models

Guidelines and principles for the conduct and publishing of economic evaluations in health and medicine, evaluating cost-effectiveness models

7.Measuring patient preferences

Concept of utilities, Rating scales, Time trade off, Multi-attribute measures

8.Pharmacoeconomic Research in Medical Centers

9.Pharmacoeconomics and Community Practice

10. The Application of Pharmacoeconomics in Managed Healthcare Settings

11. Pharmacoeconomics and Clinical Practice - A Physician's View

12. Pharmacoeconomics and Health Policy

Books Recommended

1. Pharmacoeconomics by J. Lyle Bootman, et al February 1, 1996
2. **Pharmacoeconomics'**, by Tom Walley, Alan Haycox and Angela Boland.
Pp 216. Price £29.99. London: Elsevier; 2003. ISBN 044307240X

Title: **Principles of Pharmacoeconomics, Second Edition** (1996)

Editors: Bootman JL, Townsend RJ, McGhan WF.

Publisher: Harvey Whitney Books Company, Cincinnati, OH

Institute of Pharmacy
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Semester – IX

ELECTIVE:

Course Name: Pharmaceutical Calculations

THEORY (DETAILED SYLLABUS)

L P C

3 - 3

1. Fundamentals of Measurement and Calculation
Ratio, proportion, dimensional analysis, percentage of error, measurements of weight and volume, aliquot method.
2. Systems of Weights and Measures, and Conversion
To understand the different systems of measurement used in the India and United states, with the Metric system and intersystem conversion.
3. Density and specific gravity in pharmaceutical calculations.
Density and specific gravity of liquids and use of it in calculation of weight and volume
4. Percentage and Ratio Strength Calculations
Percentage calculations of weight in volume, volume in volume and weight in weight and ratio strength
5. Dilutions, Concentration, and Proof Strength
Dilution and Concentration of liquids and solids and stock solution calculations
6. Isotonic Solutions
Calculations related to isotonicity
7. Electrolyte Solutions
Use of Milliequivalents, Millimoles and Milliosmols.
8. Interpretation of the Prescription or Medication Order
Medical abbreviations and understand and medication scheduling and patient compliance
9. Calculation of Doses, and Reducing and Enlarging of Formulas
Special dosing for the pediatric and elderly
Patient, drug dosage based on body weight and body surface area; use of Nomograms for calculation of BSA.
10. Parenteral therapy calculations
Constituted solutions, intravenous admixtures, caloric and protein requirements for parenteral nutrition, rate of flow, calculations involving “units”, etc.

Books Recommended

1. Ansel and Stoklosa. Pharmaceutical Calculations. 11th ed. Lippincott Williams & Wilkins 2001.
2. Thompson JE. A Practical Guide to Contemporary Pharmacy Practice
3. Pharmaceutical and Clinical Calculations / by Mansoor A. Khan and Indra K Reddy, 2nd edition, Technomic Publishing Co., USA, 2000
4. Dosage Calculations / by Gina Oliver and Carol Knauff, 2nd edition, Spring House, Pennsylvania, 2000

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Semester – IX

ELECTIVE

Course Name: Drug Information and Literature Evaluation

THEORY (DETAILED SYLLABUS)

L P C

3 - 3

- **Role of a Pharmacist** : as a Drug Information(DI) provider/ Responding to DI requests.
- **Introduction to Pharmacy and Medical Literature** – primary, secondary & tertiary resources.
- **Interpreting Medical Literature** :
Clinical trials, meta-analysis, observational studies, ADR interactions, Evidence Based Medicine, Specialized Articles
- **Fundamentals of medical writing**
- **Internet sources of information**
- **Interpreting promotional literature**
- **Ethical Issues confronting the DI service.**

Resources :

1. Drug Facts & Comparison
2. Mosby's Drug consult
3. AHFS Drug Information
4. USP Dispensing Information
5. Internet Resources & Databases

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Semester – IX

ELECTIVE

Course Name: Clinical Trials Management

THEORY (DETAILED SYLLABUS)

L P C

3 - 3

- **Introduction to Clinical Trials Concept, Design and Research**
- **Drug Development Process**
- **Organization and Monitoring of Clinical Trials**
- **Applied statistics for Clinical Trials**
- **Regulatory, Legal and Ethical Issues of Clinical Trials**
- **Financial aspects of Clinical Trials**
- **Reporting and Communication aspects of Clinical Trials**

Books Recommended

1. Fundamental of Clinical Trials. Lawrence M. Friedman, Curt D. Furberg and David L. DeMets. Springer verlag, New York, Inc. (Latest Edition)
2. Clinical Trials, A Practical Approach. Stuart J. Pocock. John Wiley & Sons., Ltd.(Latest Edition)
3. Clinical Trials, A Methodologic Perspective. Steven Piantadosi. John Wiley & Sons, Inc, 1997
4. Clinical Trials in oncology, 2nd Edition. Stephanie Green, Jacqueline Benedetti, John Crowley, Chapman & Hall/CRC, 2003.

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Semester – IX

ELECTIVE

Course Name: Regulatory Guidelines in Clinical Research

THEORY (DETAILED SYLLABUS)

L P C

3 - 3

1. **An overview of drug development process and regulatory guidelines for Pre and Post Marketing planning**
2. **ICH GCP guidelines for Clinical trials with special reference to following:**
 - **Institutional Review Board, Investigator, Sponsor, Investigator’s Brochure**
 - **A brief overview of above also to be referred with respect to International and Indian Good Clinical Practice guidelines.**
3. **INDA, NDA, USFDA, and WHO regulatory guidelines with special emphasis to clinical investigations.**

Books Recommended:

1. Introduction to the Pharmaceutical Regulatory Process by Ira. R. Berry, Marcel Dekker Inc., New York
2. FDA Regulatory Affair: A Guide for Prescription Drugs, Medical Devices & Biologics by Douglas J. Pisano & David Mantus, CRC Press, Boca Raton.
3. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials: Volume – I & II, Pharma Book Syndicate, Hyderabad.
4. New Drug Approval Process by Richard Guarino, Marcel Dekker Inc., New York
5. <http://www.ich.org>
6. <http://www.fda.gov>
7. <http://www.who.int>

Institute of Pharmacy
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B. Pharm. Hons. (5 Year Integrated Programme)
Semester –X
Course Name: Pharmacy Practice Experience

L P C
- - 20

SERIAL NO.	SUB-COMPONENTS OF COURSE	DISTRIBUTION OF CREDITS
A	Journal Article Presentation	4
B	Case/Disease State Presentation	4
C	Clinic Project(s) and Final Evaluation	12
	Total Credits	20

DETAILED SYLLABUS

The semester X is organized as an experiential learning program in various Patient Care/Clinical Research Settings. Students would complete full time supervised education in clinical, administrative or research settings that provide additional experience in speciality areas such as paediatrics, geriatrics, infectious disease, drug information, oncology, pharmacy administration etc.

Students will work in Hospital Settings/Clinical Research Settings with clinical faculty to develop competencies in the areas of medication therapy management, pharmacotherapy, drug information and patient education.

Objectives of Clinical Pharmacy Practice Experience :

- Develop the student's ability to effectively communicate, both written and orally, with patients and other health care professionals.
- Understand the pharmacist's role within an ambulatory/community pharmacy setting.
- Develop and implement a therapeutic plan as well as assess and monitor drug therapy on a patient-specific basis.
- Utilize drug information skills through projects and patient counseling.
- Understand the pathophysiology and therapeutics of various disease states.
- Participate in management and administrative activities necessary for operation of an ambulatory/community pharmacy clinic.

Student Responsibilities:

1. Read articles pertaining to therapy prior to disease state discussions.
2. Perform appropriate literature search to answer any drug information questions posed during the rotation.
3. Actively participate in the day-to-day management and workflow of the clinic.
4. Complete projects/presentations as assigned.

A. Journal Article Presentation

CREDITS : 4

- Provide review of recent journal article in an outline format. The article's subject matter should relate to the ambulatory/community care setting.
- Prepare 30-45 minute presentation based on selected article.
- Article should be evaluated according to drug literature assessment guide and enclosed template(s).
- Student is expected to be familiar with background information pertaining to selected article.
- Presentation will be made to all clinicians; other ambulatory/community pharmacy residents or practitioners may also be present.
- Student performance will be evaluated using guidelines mentioned in the enclosed evaluation form.

Journal Article Presentation Evaluation Form

Student: _____

Evaluator: _____

Topic: _____

Date: _____

Evaluation Scale :

1=remediation required; well below expectations

2=improvement mandatory; below expectations

3= adequate; meets minimum expectations

4= very good; meets general expectations

5=superior; exceeds expectations

Organization

Appropriate time utilization 1 2 3 4 5

Appropriate data provided 1 2 3 4 5

Relevance to practice setting 1 2 3 4 5

Continuity of presentation 1 2 3 4 5

Journal Club

Reputable source	1 2 3 4 5
Objective defined	1 2 3 4 5
Study design overview	1 2 3 4 5
Evaluation of statistical analysis	1 2 3 4 5
Application of graphs/charts	1 2 3 4 5
Interpretation of results	1 2 3 4 5
Study conclusions (author vs. student)	1 2 3 4 5
Limitations of study	1 2 3 4 5
Clinical impact	1 2 3 4 5

Verbal Presentation

Clear, audible speech	1 2 3 4 5
Eye contact and mannerisms	1 2 3 4 5
Ability to handle questions	1 2 3 4 5
Clear explanation of concepts	1 2 3 4 5
Handouts Legibility/organization	1 2 3 4 5
Complements presentation	1 2 3 4 5
Format of references	1 2 3 4 5

Comments: _____

Total score: _____ / 100

B. Patient Case Presentation

credits : 4

- Student will select a patient from one of the clinics with whom he/she has actively participated in the patient's care.
- Prepare 30-45 minute powerpoint presentation with handout. Responsible for thorough review of patient history necessary to appropriately present patient.
- Evaluate patient's drug therapy and propose appropriate therapeutic modifications with adequate literature support.
- Present review of one of the patient's disease states with emphasis placed on evidence-based treatment of particular disease.
- Presentation will be made to all Clinicians/Professors ; other ambulatory/community care group participants may also be present.
- Student performance will be evaluated using guidelines mentioned in the enclosed evaluation form.

Patient Case Presentation Evaluation Form

Student: _____

Evaluator: _____

Topic: _____

Date: _____

Evaluation Scale :

1=remediation required; well below expectations

2=improvement mandatory; below expectations

3= adequate; meets minimum expectations

4= very good; meets general expectations

5=superior; exceeds expectations

Organization

Appropriate time utilization	1 2 3 4 5
Appropriate data provided	1 2 3 4 5
Relevance to practice setting	1 2 3 4 5
Continuity of presentation	1 2 3 4 5

Patient Case

History well outlined	1 2 3 4 5
Interpretation of patient data	1 2 3 4 5
Critique of drug therapy	1 2 3 4 5
Development and recommendation of therapeutic plan	1 2 3 4 5

Disease State Presentation

Pathophysiology of disease	1 2 3 4 5
Discussion of drug therapy options	1 2 3 4 5
Discussion of non-pharmacological treatment options	1 2 3 4 5
Thorough search and application of literature	1 2 3 4 5
Relevance to patient case	1 2 3 4 5

Verbal Presentation

Clear, audible speech	1 2 3 4 5
Eye contact and mannerisms	1 2 3 4 5
Ability to handle questions	1 2 3 4 5
Clear explanation of concepts	1 2 3 4 5

Handouts

Legibility/organization	1 2 3 4 5
Complements presentation	1 2 3 4 5
Format of references	1 2 3 4 5

Comments: _____

Total score: _____ / 100

C. Clinic project(s) And Final Evaluation

Credits : 12

Participate in project(s) based on clinic need with focus upon ambulatory/community practice.

Projects may include but are not limited to the following:

- retrospective chart review,
- preparation of patient education materials,
- development, marketing, and implementation of new clinic services, etc.

Clinics may be related to management of various therapies/conditions like:

1. Anticoagulation –includes patient education, dose adjustment, low molecular weight heparin (LMWH) bridge therapy.
2. Diabetes Mellitus –patients with diabetes mellitus; includes patient education and disease management.
3. Cardiovascular Risk Reduction –patients with dyslipidemia; includes patient education about lifestyle modifications and disease management.
4. Specialty Medications -Hepatitis C , rheumatoid arthritis, multiple sclerosis, and growth hormone related deficiencies etc.
5. Coronary Artery Disease (CAD) – patients currently enrolled in ongoing clinics; includes patient education and disease management for primary and secondary prevention of CAD.
6. Comprehensive Medication Reviews –involves providing face-to-face patient education, assessment of drug regimens to identify drug related problems, and recommendations to optimize drug therapy outcomes.
7. Tobacco Cessation –patients who want to stop using tobacco, involves face-to-face visits with counseling on OTC and/or prescription tobacco cessation medications and behavioral modifications to help patients quit. Or
8. Rotation in other departments/wards of the hospital/Departments of Clinical Research Organization.
9. Student performance will be evaluated using guidelines mentioned in the enclosed evaluation form.

***STUDENT PERFORMANCE EVALUATION IN THE CLINIC
PROJECT(S)***

Student Name:

Practice Site:

Clinician/Professor

Term

This form should be used to evaluate student progress towards becoming a competent pharmacy practitioner. Clinician/Professor should discuss the results of this evaluation with the student at the end of the term.

- I. Verification of Hours:** *The student has completed ----- hours in the pharmacy Practice Experience*

Please use the following scale to help evaluate the student. The lowest score on the scale, 1, indicates that the student is unable to perform the activity despite repeated demonstration and practice. The highest score on the scale, 5, indicates that the student performs at the level of a practicing pharmacist.

1	2	3	4	5	Not Applicable N/A
Is unable to perform the activity despite repeated demonstration and practice.	Has limited ability to perform the activity and often requires reinforcement	Meets and performs within the expectations of a student at this level.	Meets and performs above the expectations of a student at this level.	Performs at the level of a practicing pharmacist	Student did not have an opportunity to meet this objective

II. Interpersonal Skills – Relationship Building

1. Actively sought to meet pharmacy personnel _____
2. Communicates effectively and works collaboratively with pharmacy personnel
3. . Actively sought advice and feedback of Clinician/Professor and personnel _____

III. Practice Management Skills

1. Able to describe appropriate mechanisms for drug product and controlled ordering for the pharmacy _____
2. Uses own time efficiently and effectively
3. Able to describe and share ideas about how to conduct physician and community outreach _____

IV. Practice Management Skills – Prescription Drug Filling

1. Interprets written prescriptions for completeness
2. Uses the computer system proficiently
3. Fills prescriptions with correct medication & quantity
4. Labels prescriptions with correct directions & auxiliary labels
5. Did the student compound any medications Yes No
If “Yes”, how well did student accurately compound medications?
6. Checks the dose of the prescription
7. Accurately performs necessary pharmacy calculations
8. Reviews patient medication profile for drug-related problems such drug-drug or drug-disease interactions

V. Patient Care Skills

1. Introduces themselves to the patients in a professional, caring manner _____
2. Listens to patients and shows empathy and sensitivity to the patient’s feelings and concerns
3. Conveys confidence and a professional attitude towards patients
4. Provides information to patients or their caregivers about prescription and nonprescription medication, provides OTC Consultations.
5. Uses drug information resources effectively to answer questions
6. Refers questions to other health care professionals when appropriate

VI. Comments

What are the strengths of this student –

What does this student do well?

What areas does the student need additional practice on –

What does this student need to improve? (Use separate sheet if necessary)

Clinician/Professor Signature

Date

My Clinician/Professor reviewed this evaluation with me

Student Signature

Date